OCT 3 0 2001

K013395

Page 1 of 2

Section 10 - 510(k) Summary of Safey and Effectiveness as required by 21 CFR 807.92(c)

10.1	**Submitted by**	Ferrania S.p.A. Viale della Libertà 57 17014 Ferrania Savona (Italy)
10.2	**Contact person**	Ing. Mannella Paolo Regulatory Manager +39 0195224055 (phone) +39 0195224546 (fax). E-mail: pmannella@ferraniait.com
10.3	**Date Summary Prepared:**	July 06, 2001
10.4	**Device name:**	**Common Name:** Video image digitizer **Trade name:** LifeJet™ Video Link **Classification Name:** Medical image digitizer (per 21 CFR 892.2030)
10.5	**Predicate device:**	CHILI® Video (510(k) number: K000411), Steinbeis-Transferzentrum Medizinische Informatik, Im Neuenheimer Feld 517, D-69120 Heidelberg, Germany.

10.6 Description of device

The LifeJet™ Video Link is a small box that integrates the functions and the hardware of a standard personal computer based on a Pentium architecture, for the purpose of acquisition and conversion into digital format of medical images codified as analogue video signal.

10.7 Statement of intended use

The LifeJet™ Video Link is a video image digitizer for the acquisition and conversion into digital format of medical images codified as analogue video signal.

The LifeJet™ Video Link has been developed to be used together with LifeJet™ Printers to produce referral prints of images coming out from ultrasound systems or other medical equipment through the video signal output.

10.8 Comparison with predicate device

The purpose and functionality of the Ferrania LifeJet™ Video Link are substantially equivalent to the CHILI® Video system (510(k) number: K000411). The basis for the equivalence is that both of them are video capture systems based on standard

K013395
Page 2 of 2

Section 10 - 510(k) Summary of Safey and Effectiveness as required by 21 CFR 807.92(c)

hardware components and software operating systems which perform the same functions relating to image acquisition.

The only difference is that the LifeJet™ Video Link integrates the functions and the hardware of a standard personal computer based on a Pentium architecture in a small box. So, no external keyboard and monitor are necessary to use the Video Link; a dedicated user interface, composed of a LCD and a few functional keys, is mounted on the front panel of the device for its control.

The technological equivalence of the two devices and the equivalence in terms of their features are summarized in the table below.

Table of comparison of features of Predicate Device

Feature/ Specification	LifeJet™ Video Link	CHILI® Video
Operating System	RTOS	Windows NT / Linux
RAM	32 MB	Various (PC dependent)
Used to grab images from modalities which have not digital export functions	Yes	Yes
Can grab single images	Yes	Yes
Can grab sequences of images	No	Yes
Patient demographic data can be added to images	No	Yes
Input operating device	Front panel	PC Keyboard
Image grabbing triggered by an external device	Yes	No
Single channel color acquisition	Yes	Yes
Frame grabber board	Brook tree	Various
Grabbed image can be manipulated	No	No
Can be used with any device that has a video data stream output	Yes	Yes
User selectable video sources	Yes	Yes

10.9 Performance data

Not required for this type of device and its level of concern.

10.10 Conclusion

Based on the analysis of the comparisons made between the LifeJet™ Video Link and the predicate device, Ferrania S.p.A. concluded that the LifeJet™ Video Link is safe, effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Ferrania S.P.A.
% Ms. Chantel Carson
Engineering Team Leader
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K013395
Trade/Device Name: LifeJet Video Link
Video Image Digitizer
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: October 11, 2001
Received: October 15, 2001

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

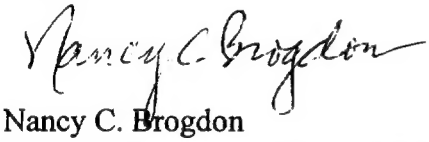
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known) K013395

Device Name: **LifeJet™ Video Link**

Indications for Use:

The LifeJet™ Video Link is a video image digitizer for the acquisition and conversion into digital format of medical images codified as analogue video signal.

The LifeJet™ Video Link has been developed to be used together with LifeJet™ Printers to produce referral prints of images coming out from ultrasound systems or other medical equipment through the video signal output.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013395